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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* NAGENDRA RANGAVAJLA

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Appeal 2015-003729
Application 12/563,157
Technology Center 1700

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Before ADRIENE LEPIANE HANLON, ROMULO H. DELMENDO, and MICHAEL P. COLAIANNI, *Administrative Patent Judges*.

COLAIANNI, *Administrative Patent Judge*

DECISION ON APPEAL

Appellant appeals under 35 U.S.C. § 134 from the final rejection of claims 1–4, 6, 7, 10–17, and 19–21. We have jurisdiction over the appeal pursuant to 35 U.S.C. § 6(b). Oral arguments were heard in this appeal on April 20, 2017.

We AFFIRM.

Appellant's invention is directed to a stabilized bacterial mixture comprising hydrolyzed mammal protein so that a probiotic organism may have improved stability during product distribution and storage (Spec. ¶ 1).

Claim 1 is illustrative:

> 1. A liquid ingestible composition comprising a probiotic stabilized in a stabilization mixture, wherein the stabilization mixture comprises, on a dry weight basis,
>
> about 70% to about 85% of one or more carbohydrates;
>
> about 10% to about 20% hydrolyzed mammalian protein, wherein at least 20% of the total hydrolyzed mammalian protein is comprised of peptides having a molecular weight of less than 2000 Daltons; and
>
> a compound binder comprising sodium alginate.

Appellant appeals the following rejections:

1. Claims 1–4, 6, 7, 10, 12–17, and 19–21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McMahon (US 2006/0233752 A1; Oct. 19, 2006) in view of Chen (US 2007/0048295 A1; Mar. 1, 2007), McGrath (US 2003/0165472 A1; Sept. 4, 2003), and Edens (US 2005/0256057 A1; Nov. 17, 2005).
2. Claim 11 is rejected under 35 U.S.C. § 103(a) as unpatentable over McMahon in view of Chen, McGrath, Edens, and Hibberd (WO 2006/124630 A2; Nov. 23, 2006).

Appellant argues claims in the following groups: (1) claims 1, 10, and–12; and (2) claim 11. With respect to group (1), we select claim 1 as representative. (App. Br. 8–13). Claims not separately argued will stand or fall with claim 1.

ANALYSIS

The Examiner's findings and conclusions regarding McMahon, Chen, McGrath and Edens as applied to claim 1 are located on pages 2 to 5 of the Answer.

Appellant argues that McMahon and Chen teach encapsulating (not stabilizing) a probiotic in solidified alginate capsules whereas Appellant forms a stabilized mixture that includes a hydrolyzed mammalian protein with at least one carbohydrate and sodium alginate (App. Br. 12–13, 20). Appellant contends that Chen's alginate encapsulation coating includes up to about 5% of pancreatic digested protein (i.e., hydrolyzed mammalian protein) and from about 1 to 3% sodium alginate, each of which concentration is outside the claimed ranges for the protein and alginate (App. Br. 13). Appellant contends that McMahon, Chen, McGrath and Edens fail to teach a probiotic stabilizing composition having about 70% to about 85% of one or more carbohydrates and about 10% to about 20% hydrolyzed mammalian protein wherein at least 20% of the total hydrolyzed mammalian protein is comprised of peptides having a molecular weight of less than 2000 Daltons (App. Br. 18–23). Appellant argues that a skilled artisan would not have incorporated Chen's solidified capsules in McMahon's infant formula because this would result in a nutritional composition for infants that would have hardened, solidified capsules in the formulation (App. Br. 19).

Appellant does not provide any citation to the Specification or elsewhere that would differentiate the meaning of "stabilization mixture" in the claim from an encapsulated probiotic as in Chen. The Specification describes that encapsulation and stabilization techniques used for shielding a

probiotic form a protective layer or matrix so that the probiotic may pass to the appropriate location within the individual's gastrointestinal (GI) tract (Spec. ¶ 3). The Specification describes "improved stability" means that a greater percentage of probiotic cells are viable after processing, transportation and storage conditions (Spec. ¶ 17). In other words, stabilized within the meaning of the claim includes forming a shielding layer around the probiotic to protect it and to provide for better shelf-life and survival of the probiotic in the GI tract of an individual.

Based upon our construction of "stabilized", we find that Chen teaches that the alginate/protein coating provides an enhanced shelf-life and survival of the probiotic in the GI tract of an individual (Chen ¶¶ 26, 38, 47, 48). Chen's coating, therefore, constitutes a stabilization mixture for shielding the probiotic from degradation during storage and use and, therefore, is not excluded from the claim. Claims 1 and 10 as interpreted in light of the Specification do not require a homogeneous mixture of the stabilized probiotic and ingestible material or infant formula. Claim 12 is the only argued claim that specifically recites an infant formula.

Regarding Appellant's argument that Chen (or that other of the applied prior art) does not teach a sodium alginate amount or a pancreatic digested protein (i.e., hydrolyzed mammalian protein) amount that falls within the claimed ranges, the Examiner finds that the sodium alginate amount and pancreatic digested protein amount are result-effective variables that would have been optimized (Final Act. 7; Ans. 8). Appellant does not dispute or otherwise show error with this finding. Moreover, Appellant's argument amounts to attacking the references individually instead of

addressing what the combined teachings would have suggested to the ordinarily skilled artisan. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

Moreover, Chen teaches that the capsule size is determined by the internal diameter of the needle on the syringe (¶ 34). The capsule sizes include diameters less than 5000 microns (i.e., 5 mm). *Id.* Chen exemplifies a capsule size of 0.5 mm (¶ 43). Chen teaches that the microcapsules were placed in milk (¶ 45). McMahon teaches that the encapsulated probiotics may be used in infant formulations (¶ 69). The combined teachings of Chen and McMahon would have suggested making the alginated capsules small enough to be suitable for infant formulations including beverages so that an infant could ingest the formulation.

Appellant argues that McGrath teaches away from use of a stabilized probiotic component in a liquid composition (App. Br. 13). Appellant contends that McGrath teaches forming a composition that is substantially free of water and the product may be freeze-dried, lypophilised or spray dried (App. Br. 13).

The Examiner cites McGrath to teach forming a matrix to protect a probiotic that includes a cryoprotectant such as trehalose, which is a limitation in claim 12 (Ans. 4). McGrath's teaching to form stabilized probiotic substantially free of water does not teach away from using a stabilized probiotic in a liquid composition. Rather, McGrath teaches a preference for having a dried product substantially free of water (McGrath ¶ 26). McGrath discloses that the stabilized probiotics can be formed in gel form and placed in a liquid feed stream that includes solid or semi-solid or liquid nutrient (McGrath ¶¶ 25, 51–53, 74–75). McGrath's disclosure parallels Appellant's disclosure that includes forming a stabilized probiotic

by freeze-drying, ambient air drying, vacuum drying, or spray drying (Spec. ¶ 18). The dried, stabilized probiotic can be used in infant, prenatal, and children's nutritional products (Spec. ¶ 18). We find, therefore, that McGrath does not teach away from using the stabilized probiotic in a liquid. Moreover, McMahon teaches that an encapsulated probiotic is used in infant formula (McMahon ¶¶ 54, 68, 69). Accordingly, the combined teachings would have taught to use a stabilized probiotic in a liquid (i.e., infant formula).

Appellant argues that McGrath is non-analogous art because its disclosure is directed to providing a feed stream which is a substantially continuous train, trail or stream of food for feeding livestock (App. Br. 14–15). Appellant contends that one of ordinary skill in the art would not have looked to McGrath's teachings regarding livestock feeding in developing probiotic compositions for ingestion by infants or human children (App. Br. 15).

Appellant's analysis does not explain why McGrath is not the same field of endeavor for at least claims 1 and 10, which are not limited to human consumption or infant formula. With regard to claims 1, 10, and 12 (i.e., an infant formula), Appellant does not explain why McGrath is not reasonably pertinent to Appellant's problem (i.e., developing a probiotic stabilizer that provides good shelf-life in a moist environment and may be shipped over long distances) (Spec. ¶¶ 1, 6, 11). The Examiner relies on McGrath to teach the stabilizing effect of trehalose on a probiotic matrix (Final Act. 7). Indeed, McGrath teaches that the probiotic composition may be kept in a "moist" state for extended periods of time without compromising the viability of the microorganism (i.e., the probiotic)

(McGrath ¶ 27). Accordingly, we find that McGrath is reasonably pertinent to Appellant's problem and is analogous art.

Appellant argues that Edens is directed to a method of cleaving a protein with an endoprotease to produce certain tripeptides (App. Br. 14). Appellant contends that Edens does not teach stabilizing a probiotic according to the present claims (App. Br. 14).

Contrary to Appellant's argument, the Examiner cites Edens to teach that it is known to hydrolyze a protein into smaller fragments so as provide a protein hydrolysate with good gastrointestinal uptake of the proteins or low allergenic properties for medical applications (Edens ¶¶ 2, 23; Ans. 4–5, 10). The Examiner finds that Edens teaches hydrolyzing the protein into fragments having molecular weight between 200 to 2000 Daltons to lower the allergenicity of the protein (Ans. 10). The Examiner finds that one of ordinary skill in the art would have used Edens' teachings to produce a hydrolyzed mammalian protein between 200 to 2000 Daltons for use in McMahon's probiotic stabilized as taught by Chen and McGrath in order to reduce the allergic nature of the protein and improve gastrointestinal uptake of the protein (Ans. 4–5, 10). Appellant does not show reversible error with the Examiner's analysis. Appellant's argument that Edens fails to teach stabilizing a probiotic improperly attacks the references individually instead of addressing what the combined teachings of McMahon, Chen, McGrath, and Edens would have suggested. *Keller*, 642 F.2d at 425.

On this record, we affirm the Examiner's § 103 rejection of claims 1–4, 6, 7, 10, 12–17, and 19–21 over McMahon in view of McGrath, Chen, and Edens.

REJECTION 2: CLAIM 11

Appellant argues that Hibberd is directed to increasing the efficacy of vaccines and does not teach administration of non-viable probiotics via an infant formula as claimed (App. Br. 16). Appellant argues that Hibberd is directed to treating the non-infant population, including children, adults and the elderly and would not have suggested including its teachings in an infant formula (App. Br. 16). Appellant argues that McMahon indicates that studies on adults are not useful in evaluating the effect of lactobacillus rhamnosus (LGG) on infants such that there would have been no motivation to use Hibberd's teaching regarding the inactivated LGG with McMahon's composition meant for infants (App. Br. 17).

Appellant's argument is undermined by Hibberd's teaching that the probiotic may be administered to any human including children under 2 years old (Hibberd 4). Hibberd teaches that the probiotic formulation can be applied to a human of "any age." *Id.* Hibberd teaches that subjects amenable to treatment with the probiotic compositions include an infant, toddler or child. *Id.* Accordingly, Hibberd's teaching to use the probiotic composition with children under 2, including infants, would have suggested combining the dead LGG with McMahon's infant formula composition.

On this record, we affirm the Examiner's § 103 rejection of claim 11 over McMahon in view of Chen, McGrath, Edens, and Hibberd.

## DECISION

The Examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136.

AFFIRMED